

Program Requirements Document Companywide	<b>2.3 AUDITOR/LEAD AUDITOR QUALIFICATION AND CERTIFICATION</b>	Identifier: PRD-5073 Revision: 3 Page: 1 of 9
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Manual: 13A—Quality and Requirements Management Program Documents

Change Number: 87317

## 1. PURPOSE

Program Requirements Document (PRD) identifies requirements and responsibilities for QA program *auditor* (see def.) *qualification* (see def.) and *lead auditor* (see def.) *qualification/certification* (see def.). See Appendix A for requirements basis.

## 2. APPLICABILITY

This PRD applies to company organizations performing QA *audit* (see def.) activities.

## 3. RESPONSIBILITIES

### 3.1 Cognizant Quality Function/Audit Managers

*Cognizant Quality Function* (CQF; see def.)/Audit Managers are responsible for submitting documentation of a prospective auditor's/lead auditor's work history/experience to the certifying authority.

### 3.2 Independent Oversight Organization

The independent oversight organization is responsible for:

- A. Appointing a certifying authority.
- B. Providing for auditor/lead auditor training.
- C. Providing for a written examination of prospective lead auditors.
- D. Ensuring that records of auditor/lead auditor qualification are established and maintained.

### 3.3 Certifying Authority

The Certifying Authority is responsible for:

- A. Evaluating *objective evidence* (see def.) to determine acceptability for auditor/lead auditor qualification against criteria in this PRD.
- B. Qualifying auditors and lead auditors, and certifying lead auditors.

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### 3.4 Lead Auditors

Lead auditors are responsible for counseling and/or evaluating prospective auditors/lead auditors and documenting their proficiency.

## 4. REQUIREMENTS

### 4.1 Companywide Applications

Requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

#### 4.1.1 Basic

4.1.1.1 Auditors and lead auditors shall be trained, qualified, and certified in accordance with the requirements of this PRD and PRD-5072, 2.2 Personnel Training and Qualification. *[NQA-1-1997, Requirement 2, 200, 300, 400, and 500]*

#### 4.1.2 Auditor Qualifications

4.1.2.1 Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. *[NQA-1-1997, Requirement 2, 304 2s; DOE/RW-0333P 18.2.13.1s]*

4.1.2.2 Competence of personnel for performing the various auditing functions shall be developed by one or more of the following methods *[NQA-1-1997, Requirement 2, 304 3s; DOE/RW-0333P 18.2.13.2s]*:

- A. Orientation to provide a working knowledge and understanding of NQA-1-1997 and DOE/RW-0333P, and the auditing organization's procedures for implementing audits and reporting results. *[NQA-1-1997, Requirement 2, 304(a); DOE/RW-0333P 18.2.13.A]*
- B. General and specialized training in audit performance, where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing; and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings. *[NQA-1-1997, Requirement 2, 304(b); DOE/RW-0333P 18.2.13.B.1 and 18.2.13.B.2]*

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- C. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits. *[NQA-1-1997, Requirement 2, 304(c) 1s and 304(c) 2s; DOE/RW-0333P 18.2.13.C.1s and 18.2.13.C.2s]*

#### 4.1.3 Lead Auditor Qualifications and Certification

A lead auditor shall be capable of organizing and directing audits, reporting audit findings, and evaluating planned and taken corrective actions. An individual shall meet the following requirements prior to being designated as a lead auditor. *[NQA-1-1997, Requirement 2, 303 1s and 303 2s; DOE/RW-0333P 18.2.14.A and 18.2.14.B]*

##### Communication Skills

- 4.1.3.1 The prospective lead auditor shall be capable of effective written and oral communication. These skills shall be attested to in writing by the lead auditor's employer. *[NQA-1-1997, Requirement 2, 303.1 1s and 303.1 2s; DOE/RW-0333P 18.2.16]*

##### Training

- 4.1.3.2 Prospective lead auditors shall receive training to the extent necessary to assure auditing competence including *[NQA-1-1997, Requirement 2, 303.2; DOE/RW-0333P 18.2.17.A]*:
- A. Knowledge and understanding of requirement *documents* (see def.) and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable. *[NQA-1-1997, Requirement 2, 303.2(a); DOE/RW-0333P 18.2.17.B.1]*
  - B. General structure of QA programs as a whole and applicable elements as defined in requirement documents. *[NQA-1-1997, Requirement 2, 303.2(b); DOE/RW-0333P 18.2.17.B.2]*
  - C. Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; closing out audit findings. *[NQA-1-1997, Requirement 2, 303.2(c); DOE/RW-0333P 18.2.17.B.3]*
  - D. Planning audits of *activities affecting quality* (see def.). *[NQA-1-1997, Requirement 2, 303.2(d); DOE/RW-0333P 18.2.17.B.4]*
  - E. On-the-job training to include applicable elements of the audit program. *[NQA-1-1997, Requirement 2, 303.2(e); DOE/RW-0333P 18.2.17.B.5]*

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#### Audit Participation

- 4.1.3.3 Prospective lead auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed three years prior to the date of qualification and certification, one audit of which shall be a *nuclear quality assurance audit* (see def.) within the year prior to qualification and certification. [NQA-1-1997, Requirement 2, 303.3; DOE/0333P 18.2.18.1s]

#### Examination

- 4.1.3.4 Prospective lead auditors shall pass an examination which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof. [NQA-1-1997, Requirement 2, 303.4 1s and 303.4 2s; DOE/RW-0333P 18.2.19.A]
- 4.1.3.5 The development and administration of the examination for a lead auditor is the responsibility of the auditing organization. The auditing organization shall develop and maintain objective evidence regarding the type and content of the examination. [DOE/RW-0333P 18.2.19.B.1s and 18.2.19.B.2s]

#### Maintenance of Proficiency

- 4.1.3.6 Lead auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to the QA program and program auditing; or participation in training program(s). [NQA-1-1997, Requirement 2, 303.5 1s; DOE/RW-0333P 18.2.21.A]
- 4.1.3.7 Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Management evaluations shall be documented. [DOE/RW-0333P 18.2.21.B.1s and 18.2.21.B.3s]

**NOTE:** *Based on annual assessment, management may extend the qualification, require retraining, or require requalification.* [NQA-1-1997, Requirement 2, 303.5 2s; DOE/RW-0333P 18.2.21.B.2s]

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### Requalification

- 4.1.3.8 Lead auditors who fail to maintain their proficiency for a period of two years or more shall be required to requalify. Requalification shall include retraining in accordance with the requirements of Paragraph 4.1.3.2 of this PRD, reexamination in accordance with the requirements of paragraph 4.1.3.4 of this PRD, and participation as an auditor in at least one nuclear quality assurance audit.  
*[NQA-1-1997, Requirement 2, 303.6 1s and 303.6 2s;  
DOE/RW-0333P 18.2.21.C.1s and 18.2.21.C.2s]*

### Certification of Qualification

- 4.1.3.9 Each lead auditor shall be certified by the auditing organization as being qualified to lead audits. *[DOE/RW-0333P 18.2.20.1s]*
- 4.1.3.10 The qualification of lead auditor personnel shall be certified in writing and shall document the following information. *[NQA-1-1997, Requirement 2, 400(a); DOE/RW-0333P 18.2.20.2s]*
- A. Employer's name. *[NQA-1-1997, Requirement 2, 400(a)(1); DOE/RW-0333P 18.2.20.A]*
  - B. Identification of person being certified. *[NQA-1-1997, Requirement 2, 400(a)(2); DOE/RW-0333P 18.2.20.B]*
  - C. Activities certified to perform. *[NQA-1-1997, Requirement 2, 400(a)(3)]*
  - D. Basis of qualification to include *[NQA-1-1997, Requirement 2, 400(a)(4); DOE/RW-0333P 18.2.20.D]*:
    - 1. education, experience, indoctrination, and training *[NQA-1-1997, Requirement 2, 400(a)(4)(a)]*
    - 2. test results, where applicable *[NQA-1-1997, Requirement 2, 400(a)(4)(b)]*
    - 3. capability demonstration results. *[NQA-1-1997, Requirement 2, 400(a)(4)(c)]*
  - E. Results of periodic evaluation. *[NQA-1-1997, Requirement 2, 400(a)(5)]*
  - F. Results of physical examinations, when required. *[NQA-1-1997, Requirement 2, 400(a)(6)]*

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G. Signature of employer's designated representative responsible for such certification. *[NQA-1-1997, Requirement 2, 400(a)(7); DOE/RW-0333P 18.2.20.E]*

H. Date of certification or recertification and certification expiration. *[NQA-1-1997, Requirement 2, 400(a)(8); DOE/RW-0333P 18.2.20.C]*

4.1.3.11 The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. *[NQA-1-1997, Requirement 2, 400(b) 1s]*

4.1.3.12 The auditing organization shall maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the auditing organization in accordance with Subsection 4.1.5 of this PRD. *[DOE/RW-0333P 18.2.19.B.1; NQA-1-1997, Requirement 2, 400(b) 3s and 400(b) 4s]*

#### Qualification Credits Scoring System

4.1.3.13 The prospective lead auditor shall have verifiable evidence that a minimum of 10 credits have been accumulated under the following scoring system *[DOE/RW-0333P 18.2.15]*:

A. Education (four credits maximum) *[DOE/RW-0333P 18.2.15.A]*:

1. an Associate's Degree from an accredited institution scores one credit; if the degree is in engineering, physical sciences, mathematics, or QA, it scores two credits; or *[DOE/RW-0333P 18.2.15.A.1.1s and 18.2.15.A.1.2s]*
2. a Bachelor's Degree from an accredited institution scores two credits; if the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits *[DOE/RW-0333P 18.2.15.A.2.1s]*
3. in addition, score one credit for a Master's Degree in engineering, physical sciences, business management, or QA from an accredited institution. *[DOE/RW-0333P 18.2.15.A.2.2s]*

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- B. Experience (nine credits maximum)—Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization’s area of responsibility scores one credit for each full year, with a maximum of five credits for this aspect of experience. *[DOE/RW-0333P 18.2.15.B]*:
1. if two years of this experience have been in the nuclear-related field, score one additional credit; or *[DOE/RW-0333P 18.2.15.B.1]*
  2. if two years of this experience have been in QA, score two additional credits; or *[DOE/RW-0333P 18.2.15.B.2]*
  3. if two years of this experience have been in auditing, score three additional credits; or *[DOE/RW-0333P 18.2.15.B.3]*
  4. if two years of this experience have been in nuclear-related QA, score three additional credits; or *[DOE/RW-0333P 18.2.15.B.4]*
  5. if two years of this experience have been in nuclear-related QA auditing, score four additional credits. *[DOE/RW-0333P 18.2.15.B.5]*
- C. Professional Competence (two credits maximum)—For certification of competency in engineering science or QA specialties issued and approved by a state agency or national professional or technical society, score two credits. *[DOE/RW-0333P 18.2.15.C]*
- D. Rights of Management (two credits maximum)—When determined appropriate, the auditing organization may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses). *[DOE/RW-0333P 18.2.15.D]*

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#### **4.1.4 Technical Specialist Qualification**

- 4.1.4.1 *Technical specialists* (see def.) selected for auditing assignments shall be indoctrinated and trained in accordance with PRD-5072, 2.2 Personnel Training and Qualification, and shall have the level of experience or training commensurate with the scope, complexity, or special nature of the work being audited. [DOE/RW-0333P 18.2.12]

#### **4.1.5 Records**

- 4.1.5.1 All records designated in implementing documents as *quality assurance records* (see def.) shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. [Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]

## **5. DEFINITIONS**

Refer to LST-199, Definitions, in the QA PRD Manual for definitions of the following terms:

*activities affecting quality*

*audit*

*auditor*

*certification*

*cognizant quality function*

*documents*

*lead auditor*

*nuclear quality assurance audit*

*objective evidence*

*qualification (personnel)*

*quality assurance audit*

*quality assurance records*

*technical specialists*

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## **6. REFERENCES**

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

## **7. APPENDICES**

Appendix A, 2.3 Basis

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### 2.3 Basis

Source	Citation	Requirement	Comments
ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 2	200, 300, 400, and 500	4.1.1.1	Consensus Requirement (CR)
NQA-1-1997, Requirement 2	303 1s and 303 2s	4.1.3	CR
NQA-1-1997, Requirement 2	303.1 1s and 303.1 2s;	4.1.3.1	CR
NQA-1-1997, Requirement 2	303.2	4.1.3.2	CR
NQA-1-1997, Requirement 2	303.2(a)	4.1.3.2.A	CR
NQA-1-1997, Requirement 2	303.2(b)	4.1.3.2.B	CR
NQA-1-1997, Requirement 2	303.2(c)	4.1.3.2.C	CR
NQA-1-1997, Requirement 2	303.2(d)	4.1.3.2.D	CR
NQA-1-1997, Requirement 2	303.2(e)	4.1.3.2.E	CR
NQA-1-1997, Requirement 2	303.3	4.1.3.3	CR
NQA-1-1997, Requirement 2	303.4 1s and 303.4 2s	4.1.3.4	CR
NQA-1-1997, Requirement 2	303.5 1s	4.1.3.6	CR
NQA-1-1997, Requirement 2	303.5 2s	4.1.3.7 Note	CR
NQA-1-1997, Requirement 2	303.6 1s and 303.6 2s	4.1.3.8	CR
NQA-1-1997, Requirement 2	304 (b)	4.1.2.2.B	CR
NQA-1-1997, Requirement 2	304 2s	4.1.2.1	CR
NQA-1-1997, Requirement 2	304 3s	4.1.2.2	CR
NQA-1-1997, Requirement 2	304(a)	4.1.2.2.A	CR
NQA-1-1997, Requirement 2	304(c) 1s and 304(c) 2s	4.1.2.2.C	CR
NQA-1-1997, Requirement 2	400(a)	4.1.3.10	CR
NQA-1-1997, Requirement 2	400(a)(1)	4.1.3.10.A	CR
NQA-1-1997, Requirement 2	400(a)(2)	4.1.3.10.B	CR
NQA-1-1997, Requirement 2	400(a)(3)	4.1.3.10.C	CR
NQA-1-1997, Requirement 2	400(a)(4)	4.1.3.10.D	CR
NQA-1-1997, Requirement 2	400(a)(4)(a)	4.1.3.10.D.1	CR
NQA-1-1997, Requirement 2	400(a)(4)(b)	4.1.3.10.D.2	CR
NQA-1-1997, Requirement 2	400(a)(4)(c)	4.1.3.10.D.3	CR
NQA-1-1997, Requirement 2	400(a)(5)	4.1.3.10.E	CR
NQA-1-1997, Requirement 2	400(a)(6)	4.1.3.10.F	CR
NQA-1-1997, Requirement 2	400(a)(7)	4.1.3.10.G	CR
NQA-1-1997, Requirement 2	400(a)(8)	4.1.3.10.H	CR

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Source	Citation	Requirement	Comments
NQA-1-1997, Requirement 2	400(b) 1s	4.1.3.11	CR
NQA-1-1997, Requirement 2	400(b) 3s and 400(b) 4s	4.1.3.12	CR
DOE/RW-0333P	18.2.12	4.1.4.1	CR
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	18.2.13.1s	4.1.2.1	CR
DOE/RW-0333P	18.2.13.2s	4.1.2.2	CR
DOE/RW-0333P	18.2.13.A	4.1.2.2.A	CR
DOE/RW-0333P	18.2.13.B.1 and 18.2.13.B.2	4.1.2.2.B	CR
DOE/RW-0333P	18.2.13.C.1s and 18.2.13.C.2s	4.1.2.2.C	CR
DOE/RW-0333P	18.2.14.A and 18.2.14.B	4.1.3	CR
DOE/RW-0333P	18.2.15	4.1.3.13	CR
DOE/RW-0333P	18.2.15.A	4.1.3.13.A	CR
DOE/RW-0333P	18.2.15.A.1.1s and 18.2.15.A.1.2s	4.1.3.13.A.1	CR
DOE/RW-0333P	18.2.15.A.2.1s	4.1.3.13.A.2	CR
DOE/RW-0333P	18.2.15.A.2.2s	4.1.3.13.A.3	CR
DOE/RW-0333P	18.2.15.B	4.1.3.13.B	CR
DOE/RW-0333P	18.2.15.B.1	4.1.3.13.B.1	CR
DOE/RW-0333P	18.2.15.B.2	4.1.3.13.B.2	CR
DOE/RW-0333P	18.2.15.B.3	4.1.3.13.B.3	CR
DOE/RW-0333P	18.2.15.B.4	4.1.3.13.B.4	CR
DOE/RW-0333P	18.2.15.B.5	4.1.3.13.B.5	CR
DOE/RW-0333P	18.2.15.C	4.1.3.13.C	CR
DOE/RW-0333P	18.2.15.D	4.1.3.13.D	CR
DOE/RW-0333P	18.2.16	4.1.3.1	CR
DOE/RW-0333P	18.2.17.A	4.1.3.2	CR
DOE/RW-0333P	18.2.17.B.1	4.1.3.2.A	CR
DOE/RW-0333P	18.2.17.B.2	4.1.3.2.B	CR
DOE/RW-0333P	18.2.17.B.3	4.1.3.2.C	CR
DOE/RW-0333P	18.2.17.B.4	4.1.3.2.D	CR
DOE/RW-0333P	18.2.17.B.5	4.1.3.2.E	CR
DOE/RW-0333P	18.2.18.1s	4.1.3.3	CR
DOE/RW-0333P	18.2.19.A	4.1.3.4	CR

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Source	Citation	Requirement	Comments
DOE/RW-0333P	18.2.19.B.1	4.1.3.12	CR
DOE/RW-0333P	18.2.19.B.1s and 18.2.19.B.2s	4.1.3.5	CR
DOE/RW-0333P	18.2.20.1s	4.1.3.9	CR
DOE/RW-0333P	18.2.20.2s	4.1.3.10	CR
DOE/RW-0333P	18.2.20.A	4.1.3.10.A	CR
DOE/RW-0333P	18.2.20.B	4.1.3.10.B	CR
DOE/RW-0333P	18.2.20.C	4.1.3.10.H	CR
DOE/RW-0333P	18.2.20.D	4.1.3.10.D	CR
DOE/RW-0333P	18.2.20.E	4.1.3.10.G	CR
DPE/RW-0333P	18.2.21.A	4.1.3.6	CR
DOE/RW-0333P	18.2.21.B.2s	4.1.3.7 Note	CR
DOE/RW-0333P	18.2.21.C.1s and 18.2.21.C.2s	4.1.3.8	CR
DOE/RW-0333P	18.21.B.1s and 18.21.B.3s	4.1.3.7	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.5.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements